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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,567	07/20/2001	Roberto A. Macina	DEX-0214	4354

26259 7590 05/15/2003

LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/15/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,567

Applicant(s)

MACINA ET AL.

Examiner

Carolyn L Smith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 17.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

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DETAILED ACTION

Applicants' amendments and remarks, including the cancellation of claims 3-16, in Paper No. 16, filed 3/10/03, are acknowledged.

Applicants' arguments, filed 3/10/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1 and 2 are herein under examination.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1 (line 1) and claim 2 (line 1) recite the phrase "lung specific *gene*" which is confusing as the limitations of claim 1 are directed to a polynucleotide or a polypeptide which is not a gene. Correction of this issue by replacing "gene" with "molecule" will nullify this rejection. Claim 2 is also rejected due to its dependency from claim 1. This rejection is necessitated by amendment.

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Claim 2 is vague and indefinite as the polypeptide of SEQ ID NO: 48 is not expressed by SEQ ID NO: 12 (as stated in claim 1). An additional cytosine at position 71 of SEQ ID NO: 12 has caused the reading frame of SEQ ID NO: 48 not to match SEQ ID NO: 12.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 1 is maintained under U.S.C. 102(b) as being anticipated by Sigma (1990). Applicants argue that the teachings of the specification, particularly at pages 19-25 make clear that by the phrase “of” SEQ ID NO: 12, Applicants in no way mean to encompass an oligomer such as O 3003 that matches only a 3 nucleotide base segment of SEQ ID NO: 12. This is found unpersuasive, because O 3003 falls within the scope of claim 1 as written.

It is noted that the polypeptide limitations of claims 1 and 2 do not get the earlier priority date claimed in priority document 60/219834. Therefore, the filing date of the instant application is the earliest date used for prior art purposes regarding the polypeptide sequence of SEQ ID NO: 48.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession No. AL136666.

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GenBank Accession No. AL136666 discloses a polypeptide which is 100% identical to SEQ ID NO: 48 (see attached Sequence match listing). Therefore, GenBank Accession No. AL136666 anticipates the instant invention.

Conclusion

No claim is allowed.

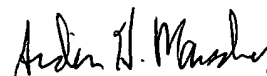
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 13, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER

09H0S4

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Query Match      100.0%; Score 2302; DB 4; Length 455;
Best Local Similarity 100.0%; Pred. No. 3.9e-165;
Matches 455; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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[illegible]

Qy	61	GRDIIGLAETGSGKGTAFALPILNALLET	PQRLFALVLTPTRELA	FQISEQFEALGSSIG	120
Db	61	GRDIIGLAETGSGKGTAFALPILNALLET	PQRLFALVLTPTRELA	FQISEQFEALGSSIG	120
Qy	121	VQSAVIVGGIDSMQSLALAKKPHII	IATPGR	LIDHLENTKGFNLRALKYLMDEADRIL	180
Db	121	VQSAVIVGGIDSMQSLALAKKPHII	IATPGR	LIDHLENTKGFNLRALKYLMDEADRIL	180
Qy	181	NMDFETEVDKILKVIPRDRKTLF	SATMTKKVKQLQRAALKNPVKCAVSSKYQTVEK	LQQ	240
Db	181	NMDFETEVDKILKVIPRDRKTLF	SATMTKKVKQLQRAALKNPVKCAVSSKYQTVEK	LQQ	240
Qy	241	YYIFIPSKFKDTYLVYILNELAGNSFMIFCSTCNNTQRTALL	LRNLGFTAIP	LHGQMSQS	300
Db	241	YYIFIPSKFKDTYLVYILNELAGNSFMIFCSTCNNTQRTALL	LRNLGFTAIP	LHGQMSQS	300
Qy	301	KRLGSLNFKKAKARSILLATDVASRGLDIP	HVDVVVNF	DIPTHSKDYIHRVGRTARAGRS	360
Db	301	KRLGSLNFKKAKARSILLATDVASRGLDIP	HVDVVVNF	DIPTHSKDYIHRVGRTARAGRS	360
Qy	361	GKAITFVTQYDVELFQRIEHLIGKKLP	GFPTQDDEV	MMLTERVAE	AQRFARMELREHGEK 420
Db	361	GKAITFVTQYDVELFQRIEHLIGKKLP	GFPTQDDEV	MMLTERVAE	AQRFARMELREHGEK 420
Qy	421	KKRSREDAGDNDDEGAIGVRN	KVAGGKMKRKRGR	455	
Db	421	KKRSREDAGDNDDEGAIGVRN	KVAGGKMKRKRGR	455	

Continuation of Attachment(s) 6). Other: Sequence Match Listing (1 page).